§170.315(b)(2) Clinical information reconciliation and incorporation

2015 Edition Cures Update CCG

Version 1.0 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	06-15-2020

Regulation Text

Regulation Text

§ 170.315 (b)(2) *Clinical information and reconciliation and incorporation—*

(i) *General requirements*. Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) through (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates on and after May 2, 2022.

(ii) *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 170.205(a)(3) through (5), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.

(iii) *Reconciliation.* Enable a user to reconcile the data that represent a patient's active medication list, allergies and intolerance list, and problem list as follows. For each list type:

(A) Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.

(B) Enable a user to create a single reconciled list of each of the following: Medications; Allergies and Intolerances; and problems.

(C) Enable a user to review and validate the accuracy of a final set of data.

(D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s) on and after May 2, 2022:

(1) Medications. At a minimum, the version of the standard specified in § 170.213;

(2) Allergies and intolerance. At a minimum, the version of the standard specified in § 170.213; and

(3) Problems. At a minimum, the version of the standard specified in § 170.213.

(iv) *System verification.* Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template and the standard specified in § 170.205(a)(5) on and after May 2, 2022.

Standard(s) Referenced

Paragraphs (b)(2)(i) and (ii)

§ 170.213 United States Core Data for Interoperability (USCDI)

§ 170.205(a)(3) Health Level 7 (HL7®) Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012

§ 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 August 2015, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5)

Paragraphs (b)(2)(iii)(B) – (D)

§ 170.213 United States Core Data for Interoperability (USCDI)

Paragraph (b)(2)(iv)

§ 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 August 2015, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5)

Certification Companion Guide: Clinical information reconciliation and incorporation

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule). It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the ONC Cures Act Final Rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(2). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(b) "paragraph (b)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging", which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))

- Auditable events and tamper-resistance (§ 170.315(d)(2))
- Audit reports (§ 170.315(d)(3))
- Automatic access time-out (§ 170.315(d)(5))
- Emergency access (§ 170.315(d)(6))
- End-user device encryption (§ 170.315(d)(7))
- Integrity (§ 170.315(d)(8))
- Encrypt authentication credentials (§ 170.315(d)(12))
- Multi-factor authentication (MFA) (§ 170.315(d)(13))

- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces that enable the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.
- Consolidated-Clinical Document Architecture (C-CDA) creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance Certification Companion Guide for more details.

Table for Design and Performance

- Safety-enhanced design (§ 170.315(g)(3))
- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))
- Consolidated CDA creation performance (§ 170.315(g)(6))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The scope of this criterion is limited to the C-CDA Continuity of Care Document (CCD), Referral Note, and (inpatient setting only) Discharge Summary document templates. [see also 80 FR 62639]
- In combination with the C-CDA R2.1 standard, developers certifying to the USCDI must follow the guidance and templates provided in HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2 for implementation of the C-CDA Release 2.1 standard. For example, details on how to structure and exchange Clinical Notes are included in the C-CDA Companion Guide.
- "Incorporation" means to electronically process structured information from another source such that it is combined (in structured form) with information maintained by health IT and is subsequently available for use within the health IT system by a user. [see also 77 FR 54168 and 77 FR 54218]
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see Frequently Asked Questions #51 Certified health IT adoption of, and compliance with, the corrections are necessary because they update vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. There is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., C-CDA 2.1 Validator). Similarly, there

will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Program.

Paragraph (b)(2)(i)

Clarifications:

- We are requiring Health IT Modules to be able to reconcile and incorporate information from C-CDAs formatted to both C-CDA Releases 1.1 and 2.1. While Release 2.1 largely ensures compatibility between C-CDA Release 1.1 and 2.0, it does not guarantee compatibility without further development effort. [see also 80 FR 62639]

Paragraph (b)(2)(ii)

Technical outcome – The health IT can properly match a received Transition of Care (ToC)/Referral Summary (for both Releases 1.1 and 2.1) to the correct patient.

Clarifications:

- Health IT Modules do not have to auto-match the patient. Manual patient match is acceptable as long as the received C-CDA can be matched to the correct patient. [see also 80 FR 62640 and 77 FR 54219]

Paragraph (b)(2)(iii)(A)

Technical outcome – A user can simultaneously display a patient's active data, and its attributes, from at least two of the following sources: a patient's medication list, allergies and intolerances list, and problem list. Displayed data attributes must include the source and the last modification date.

Clarifications:

- A vendor must enable a user to electronically and simultaneously display (that is, in a single view) the data from at least two list sources. If the two lists cannot be displayed in the tool at the same time, then this does not constitute a single view and does not meet the requirements for the certification criterion.

Paragraphs (b)(2)(iii)(B) - (D)

Technical outcome – A user can review, validate, and incorporate a patient's medication list (using RxNorm), allergies and intolerances list (using RxNorm), and problem list (using SNOMED CT®).

Clarifications:

- The health IT can enable a user to review, validate, and incorporate medications, medication allergies, and problems in distinct functions, or combined, as long as all three can be demonstrated. [see also 80 FR 62639]
- Testing will evaluate health IT ability to incorporate data from C-CDA documents with variations in the data elements to be reconciled to test real-world variation that may be found in C-CDA documents. [see also 80 FR 62639]
- ONC encourages developers to incorporate data in a structured format. [see also 77 FR 54219]
- Incorporation does not have to be automated. [see also 77 FR 54219]
- Health IT Modules can present for certification to a more recent version of RxNorm than what is currently in USCDI v1 per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than what is currently in USCDI v1 per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  - RxNorm OID: 2.16.840.1.113883.6.88.
  - SNOMED CT® OID: 2.16.840.1.113883.6.96. [see also 80 FR 62612]

Paragraph (b)(2)(iv)

Technical outcome – The health IT can create a C-CDA document (using the CCD template in C-CDA Release 2.1) that includes the reconciled and incorporated data.

Clarifications:

- No additional clarifications.

Content last reviewed on June 22, 2020